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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,070	03/03/2006	Sutisak Kitareewan	DC0266/US.NP	5026
26259 7590 04/21/2010 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER MARTIN, PAUL C				
ART UNIT 1657		PAPER NUMBER		
NOTIFICATION DATE 04/21/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

porcilly@licataandtyrrell.com

# Office Action Summary

**Application No.**

10/564,070

**Applicant(s)**

KITAREEWEAN ET AL.

**Examiner**

PAUL C. MARTIN

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) g is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) g is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claim 8 is pending in this application and was examined on its merits.

The rejection of Claim 1 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, because the specification, while being enabling for a method of identifying an agent which destabilizes lysosomes, does not reasonably provide enablement for a method to identify any agent which destabilizes lysosomes and increases any oncogenic or aberrant protein degradation; has been withdrawn due to the Applicant's cancellation of the Claim in the reply filed 02/23/2010.

The rejection of Claim 1 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn due to the Applicant's cancellation of the Claim in the reply filed 02/23/2010.

The rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Schütt *et al.* (2002) has been withdrawn due to the Applicant's cancellation of the Claim in the reply filed 02/23/2010.

The rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Öllinger *et al.* (1995) has been withdrawn due to the Applicant's cancellation of the Claim in the reply filed 02/23/2010.

The rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Weeks *et al.* (1996) has been withdrawn due to the Applicant's cancellation of the Claim in the reply filed 02/23/2010.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 02/23/2010, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, 2<sup>nd</sup> paragraph and 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yoshida *et al.* (1996) in view of Bard *et al.* (1977).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshida *et al.* (1996) in view of Bard *et al.* (1977).

Yoshida *et al.* teaches a method of identifying an agent that increases oncogenic protein degradation comprising contacting an APL (acute promyelocytic leukemia) cell that expresses PML/RAR $\alpha$  with the anti-cancer agent ATRA (all-*trans*-retinoic acid) and detecting whether ATRA increases PML/RAR $\alpha$  protein degradation (Pg. 2946, Column 2, Lines 22-29 and Pg. 2947, Column 1, Lines 1-5 and Fig. 4).

Yoshida *et al.* does not teach a method for identifying and agent which destabilizes lysosomes comprising contacting a cell that expresses PML/RAR $\alpha$  with an agent and detecting whether the agent destabilizes lysosomes of the cell as determined by vital staining of lysosomes or release of lysosomal proteins into the cytosol.

Bard *et al.* teaches a method wherein cartilage cells are contacted with known anticancer retinoid compounds and detecting whether the retinoids destabilize lysosomes as determined by the release of lysosomal proteins into the cytosol and the resulting degradation of the cartilage matrix as a measure of toxicity (Pg. 115, Column 1, Lines 25-36 And Column 2, Lines 1-13)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the method of Yoshida *et al.* for identifying an anti-cancer agent that increases oncogenic protein degradation with the method of Bard *et al.* for identifying an anti-cancer agent which destabilizes lysosomes because it is *prima facie* obvious to combine two methods, each taught separately as useful for screening the same anti cancer agent (retinoic acid) in order to form a single combined assay for detecting an anti-cancer agent which both destabilizes lysosomes and increases PML/RAR $\alpha$  degradation. The MPEP states:

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

### **Conclusion**

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

04/15/2010

/Rebecca E. Prouty/  
Primary Examiner,  
Art Unit 1652